



CERTIFICATE

ATTESTATION CERTIFICATE OF ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

Technical file of the company mentioned below has been observed and audit has been completed successfully.

2014/30/EU Electromagnetic Compatibility Directive and
2014/35/EU Low Voltage Directives have been taken as references for these processes

Company Name : Jinan Biobase Biotech Co., Ltd.

Company Address : Room 501,Tianqiao District Technology Center,No.6 Lanxiang
Middle Road,Tianqiao District,Jinan,China

Related Directives and Annex : 2014/35/EU Low Voltage Directive
2014/30/EU Electromagnetic Compatibility Directive

Related Standards : EN 61326-1:2013;EN 61010-1:2010

Product Name : Drying Oven

Report No and Date : 201709252104-LVD/EMC

Product Brand/Model/Type : BOV-T30C/BOV-T70C/BOV-T140C/BOV-T270C/BOV-T25F/BOV-T50F/
BOV-T105F/ BOV-T200F/BOV-V30F/BOV-V35F/BOV-V45F/BOV-V65F/
BOV-V70F/BOV-V125F/ BOV-V136F/BOV-V225F/BOV-V230F/
BOV-V429F/ BOV-V625F/ BOV-V640F/ BOV-V960F/ BOV-V27F/
BOV-V90F/BOV-V135F/ BOV-V216F/BOV-XF124/BOV-30V/BOV-50V/
BOV-90V/BOV-215V/BOV-90VL/BOV-215VL/BOV-D30/BOV-D50/BOV-D70/
BOV-D140/ BOV-D240/ BOV-H50F/BOV-H90F/BOV-H125F/BOV-H216F

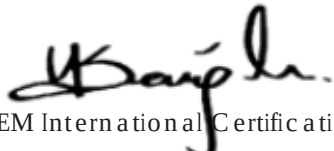
Certificate Number : M.2017.201.N2107

Initial Assessment Date : 27.09.2017

Registration Date : 28.09.2017

Reissue Date/No : -

Expiry Date : 27.09.2022


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

The validity of the certificate can be checked through www.udem.com.tr. The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be noticed in case of any changes on the product(s)

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质量管理体系 认证证书

证书号：HXC18921Q20254R0M

兹 证 明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

注册地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

办公地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

生产/经营地址：山东省济南市工业南路 51 号（生产）/济南市章丘明水经济开发区经十东路与明埠路交界
山东博科产业园（研发、生产、销售）/济南市章丘明水经济开发区清河大街 2 号鑫岳工业园 8#（生产）
/山东省济南市平阴县锦水高端装备制造产业园 3 号标准厂房（生产）

邮编：250200

质量管理体系符合

GB/T 19001-2016 / ISO 9001:2015 标准条款的要求

该体系认证所覆盖的范围

用于体外诊断试剂盒、生物安全柜、医用气溶胶吸附器、血液冷藏箱、医用恒温箱、
全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、
全自动生化分析仪、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪、
一次性使用病毒采样管、医用离心机的研发、生产和销售（资质许可范围内）

第一次监审	贴标处	第二次监审	贴标处	第三次监审	贴标处
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证书有效期内，获证组织须每年至少接受一次监督审核并加贴合格标志，证书方为有效。
本证书信息可在国家认证认可监督管理委员会官方网站：www.cnca.gov.cn查询。
证书有效性以右侧二维码扫描内容为准



张建设



初次获证日期：2021 年 7 月 5 日

签发日期：2021 年 7 月 5 日

有效日期：2024 年 7 月 4 日

北京市昌平区城北街道鼓楼南街 6 号 2 号楼 802 室

www.hxccc.org

010-57146599

No. 0002277

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. : HXC18921Q20254R0M

Awarded to

Biobase Biodustry(Shandong)Co., Ltd.

Organization Code: 9137018179889855X7

Registration Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Office Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Production/Service Add.: No.51 Industrial South road,Jinan City, Mingshui Economic Development Zone,
Zhangqiu District,Jinan City(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road),
No.2 Qinghe street, Zhangqiu District, Jinan City,Standard Plant No. 3, Jinshui High-end Equipment
Manufacturing Industrial Park, Pingyin County, Jinan City, Shandong Province

Zip Code: 250200

**The Quality Management System of the above
organization has been assessed and Found to be in accordance with
the requirements of the standard:**

GB/T 19001-2016 / ISO 9001:2015

Scope of this management Certification

**R&D, production and sales of In Vitro Diagnostic Reagents, Biological Safety Cabinets,
Air Purifier, Blood Bank Refrigerator, Medical Incubator, Automatic ELISA Processor,
Hematology Analyzer Diluent, Hematology Analyzer Lyse, Microplate Washer,
Laboratory Refrigerator, Automatic chemistry analyzer, Automatic Chemiluminescence Analyzer,
Automatic Nucleic acid extration system, Disposable Virus Sampling Tube,
Medical centrifuge (within the scope of qualification license)**

First S.A.	Labelling	Second S.A.	Labelling	Third S.A.	Labelling
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The certified organization must accept at least one surveillance audit annually and a qualified mark shall be attached onto the certificate, within validity period of the certificate, then the certificate can be maintained valid.

For more details of this certificate, please login CNCA' s website: www.cnca.gov.cn.

For the validity of the certificate, please scan the QR codes on the right ride for accurate information.



张建设



Date of Issue:5 Jul. 2021 Date of Supervision:5 Jul. 2021 Valid until:4 Jul. 2024

Room 802, 2nd Building, No. 6 South Street of Gulou, Changping District, Beijing City, China 010-57146599

No. 0002277

医疗器械质量管理体系 认证证书

证书号：HXC18921YL008R0M

兹 证 明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

注册地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

办公地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

生产/经营地址：山东省济南市工业南路 51 号（生产）/济南市章丘明水经济开发区经十东路与明埠路交界
山东博科产业园（研发、生产、销售）/济南市章丘明水经济开发区清河大街 2 号鑫岳工业园 8#（生产）
/山东省济南市平阴县锦水高端装备制造产业园 3 号标准厂房（生产）

邮编：250200

医疗器械质量管理体系符合

ISO 13485: 2016 标准要求

通过认证的范围为

用于体外诊断试剂盒、生物安全柜、医用气溶胶吸附器、血液冷藏箱、医用恒温箱、
全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、
全自动生化分析仪、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪、
一次性使用病毒采样管、医用离心机的研发、生产和销售（资质许可范围内）

第一次监审	贴标处	第二次监审	贴标处	第三次监审	贴标处
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证书有效期内，获证组织须每年至少接受一次监督审核并加贴合格标志，证书方为有效。
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010-57146599

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certification No. : HXC18921YL008R0M

Awarded to
Biobase Biodustry(Shandong)Co., Ltd.

Organization Code: 9137018179889855X7

Registration Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
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No.2 Qinghe street, Zhangqiu District, Jinan City,Standard Plant No. 3, Jinshui High-end Equipment
Manufacturing Industrial Park, Pingyin County, Jinan City, Shandong Province

Zip Code: 250200

**The Medical Devices Quality Management Systems of the above
Organization has been assessed and Found to be in accordance with
the requirements of the standard:**

ISO 13485:2016

Scope of this management Certification

**R & D, production and sales of In Vitro Diagnostic Reagents, Biological Safety Cabinets,
Air Purifier, Blood Bank Refrigerator, Medical Incubator, Automatic ELISA Processor,
Hematology Analyzer Diluent, Hematology Analyzer Lyse, Microplate Washer,
Laboratory Refrigerator, Automatic chemistry analyzer, Automatic Chemiluminescence Analyzer,
Automatic Nucleic acid extration system, Disposable Virus Sampling Tube,
Medical centrifuge (within the scope of qualification license)**

First S.A.	Labelling	Second S.A.	Labelling	Third S.A.	Labelling
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Room 802,2nd Building,No.6 South Street of Gulou,Changping District,Beijing City,China 010-57146599

Oven

Constant-Temperature Drying Oven

Features:

- * External material: cold-rolled steel with anti-bacteria powder coating.
- * Stainless steel inner chamber, round angle structure, adjustable shelves.
- * PID control with LED display, soft touch operational key, timing function and over-temperature protection.
- * Door with double-layer tempered glass observation window, adjustable air-tight buckle lock, and silicon rubber seal, which provide good seal ability and efficiently prevent heat loss.



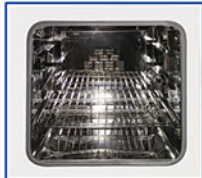
Technical Parameters:

Model	BOV-T30C	BOV-T70C	BOV-T140C	BOV-T270C
Capacity	43L	72L	137L	270L
Temp. Range	50~200℃			
Temp. Fluctuation	±1℃			
Ambient Temp.	5~40℃			
Timing Range	1~9999min			
Shelves No.	2 pcs		3 pcs	
Consumption	850W	1000W	2000W	3000W
Power Supply	AC110V/220V±10%, 50/60Hz			
Internal Size(W*D*H) mm	350*350*350	400*400*450	500*500*550	600*600*750
External Size(W*D*H) mm	630*540*550	720*570*750	820*670*850	920*770*1050
Package Size(W*D*H) mm	780*750*700	870*700*800	960*780*950	1060*880*1150
Gross Weight(kg)	60	70	105	145

Forced Air Drying Oven

Features:

- * External material: cold-rolled steel with anti-bacteria powder coating.
- * Stainless steel inner chamber, round angle structure, adjustable shelves.
- * Double-layer glass observation window, adjustable airtight buckle lock.
- * PID control with LED display.
- * Over-temperature protection.



Technical Parameters:

Model	BOV-T25F	BOV-T50F	BOV-T105F	BOV-T200F
Capacity	25L	54L	108L	212L
Temp. Range	50~200℃			
Temp. Precision	0.1℃			
Temp. Fluctuation	±1℃			
Ambient Temp.	5~40℃			
Timing Range	1~9999min			
Shelves No.	2 pcs			
Consumption	650W	1000W	1600W	2500W
Power Supply	AC110V/220V±10%, 50/60Hz			
Internal Size(W*D*H) mm	300*300*280	420*370*350	550*360*550	600*550*645
External Size(W*D*H) mm	580*500*450	710*560*530	830*610*720	880*780*820
Package Size(W*D*H) mm	710*660*620	840*690*700	960*720*900	1010*880*940
Gross Weight(kg)	51	66	115	145